

Attorney Docket No. P66403US0  
Serial No. 09/744,973

**Remarks/Arguments:**

Claims 1-8 are cancelled, without prejudice or disclaimer.

Claims 9-15, presented hereby, are pending.

Claim 9 corresponds to claim 5, revised to overcome the rejection under §112, ¶2, and claims 10 and 11 correspond to claims 6 and 7, respectively, made dependent on claim 9. Claim 12 corresponds to claim 8, revised to more clearly define the invention, and claims 13-15, which contain subject matter recited in claims 2-4, respectively, are dependent on claim 12.

The rejections of claims 1-4 under 35 USC 101 are rendered moot by cancellation of the rejected claims, hereby.

Claim 5 was rejected under 35 USC 112, ¶2, for allegedly being indefinite. Reconsideration is requested in view of the changes made to claim 5 as reflected in replacement claim 9, presented hereby.

Sucrose and glycine are added as powders. The concentrations of sucrose and glycine recited are the concentrations of sucrose (60 to 70% (w/w)) and glycine (0.1 to 0.3 M) in the resulting mixture.

Claims 1-6 were rejected under 35 USC 102(b) based on *Brazilian J. Med. Biol. Res.*, 28, 473-476, 1993 (Reis), and claims 1-8 were rejected under 35 USC 103(a) based on the teachings of WO9422503 (Martinowitz) in combination with Reis and under 35 USC 103(a) based on the teachings of WO9833533 (Nur) in combination with Reis. Reconsideration of the rejections under §102(b) and under §103(a) is requested.

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For anticipation under § 102 to exist, each and every claim limitation, as arranged in the claim, must be found in a single prior art reference. *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 225 USPQ 253 (Fed. Cir. 1985). The absence from a prior art reference of a single claim limitation negates anticipation. *Kolster Speedsteel A B v. Crucible Inc.*, 230 USPQ 81 (Fed. Cir. 1986). A reference that discloses "substantially the same invention" is not an anticipation. *Jamesbury Corp.* To anticipate the claim, each claim limitation must "*identically appear*" in the reference disclosure. *Gechter v. Davidson*, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997) (*emphasis added*). To be novelty defeating, a reference must put the public in possession of the identical invention claimed. *In re Donahue*, 226 USPQ 619 (Fed. Cir. 1985).

Reis is relied on as a novelty defeating reference in order to reject the claims under §102(b). According to the reference (Reis, page 474, especially second full paragraph, lines 1 and 2), the cryoprecipitate is prepared by so-called "double cold precipitation." Double cold precipitation is a method for purifying a cryoprecipitate and, thereby, remove fibrinogen multimers from the cryoprecipitate. In connection with this double cold precipitation, Reis (page 1 and page 4 n. 1) cites *Proceedings of the 3<sup>rd</sup> van Creveld Symposium*, 77-82, 1988 (Smit Sibinga), a copy of which is attached hereto as Appendix. attached refers to Sibinga et al., copy enclosed).

According to Smit Sabinga (pages 78-80, § Materials and Methods), purified cryoprecipitate is obtained starting with frozen plasma (in bloodbags), which is thawed at 4°C and, then, centrifuged. The resulting supernatant is removed and the cryoprecipitate is redissolved (at 37°C). This redissolved cryoprecipitate is pooled and frozen, then thawed, pooled, and centrifuged and the

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resulting supernatant is decanted and discarded. Fibrinogen monomers contained cryoprecipitate appear in the supernatant following centrifugation.

Accordingly, the decanting (and discarding) of the supernatant according to Smit Sibinga, as taught by Reis, effectively removes from the cryoprecipitate any fibrinogen multimers originally present, therein. On the contrary, in accordance with the presently claimed invention, the presence of fibrinogen multimers is a necessary feature (limitation), both, in the claimed fibrin sealant and in the fibrin sealant obtained by the claimed method. As such, a limitation on the present claims being absent from Reis, anticipation under § 102(b) based on Reis is negated, *Kolster Speedsteel AB, supra*.

Concerning the rejection under § 103(a) based on Martinowitz in view of Reis, the statement of rejection alleges that a person skilled would have been motivated to use the cryoprecipitate of Reis in the method of Martinowitz. Whether or not the allegation is correct is of no moment; even assuming *arguendo* that the skilled artisan would have been motivated to combine the teachings of the references, combined these teachings would not have resulted in the invention presently claimed.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). A "ground of rejection is simply inadequate on its face . . . [when] the cited references do not support each limitation of [the] claim." *In re Thrift*, 63 USPQ2d 2002, 2008 (Fed. Cir. 2002). When conducting an

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obviousness analysis, "all limitations of a claim must be considered in determining the claimed subject matter as is referred to in 35 U.S.C. 103 and it is error to ignore specific limitations distinguishing over the [prior art] reference." *Ex parte Murphy*, 217 USPQ 479, 481 (PO Bd. App. 1982).

As explained, above, the cryoprecipitate prepared according to Reis is free of fibrinogen multimers, which are a necessary feature of the presently claimed invention. Therefore, since "the cited references do not support each limitation of [the] claim," the rejection under §103(a) based on the cited references "is simply inadequate on its face." *Thrift*, 63 USPQ2d at 2008.

The rejection under §103(a) based on the combined teachings of Nur and Reis falls for, essentially, the same reasons as set forth above with respect to the §103(a) rejection based on the combined teachings of Martinowitz and Reis.

According to the statement of rejection, a person skilled in the art would have been motivated to use the cryoprecipitate of Reis in the method of Nur. As has been explained above, the cryoprecipitate of Reis is essentially free of fibrinogen multimers, a required feature of the presently claimed invention.. Therefore, even assuming arguendo that the skilled artisan would have been motivated to combine the teachings of Nur and Reis, the combined teachings would not have resulted in the invention presently claimed; the resulting fibrin glue would not have included multimers of fibrinogen, as required by the instant claims. As with the combined teachings of Martinowitz and Reis, the combined teachings of Nur and Reis "do not support each limitation of

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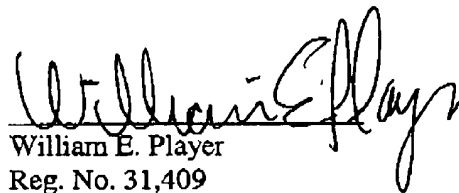
[the] claim" and, therefore, the rejection under §103(a) based on Nur in view of Reis "is simply inadequate on its face." *Thrift*, 63 USPQ2d at 2008.

Favorable action is requested.

Respectfully submitted,

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